K050789

ADMINISTRATIVE INFORMATION

MAY 2 7 2005

Manufacturer Name:	R and D Medical, LLC 1048 Irvine Avenue, Suite 354 Newport Beach, CA 92660
Official Contact:	Kathleen Swantkoski Telephone: (949) 887-8478 FAX: (949) 548-4951
Representative/Consultant:	Floyd G. Larson PaxMed International 4329 Graydon Road San Diego, CA 92130 Telephone: (858) 792-1235 FAX: (858) 792-1236 e-mail: flarson@paxmed.com

DEVICE NAME

Classification Name:	Filler, calcium sulfate preformed pellets
Trade/Proprietary Name:	Formagraft™ Collagen Bone Graft Matrix
Common Name:	Bone void filler
Product Code:	MQV

DEVICE CLASSIFICATION

Calcium sulfate preformed pellets have been classified by FDA as Class II, Special Controls, in a Final Rule effective July 2, 2003 (68 FR 32635) (21 CFR 888.3045). Calcium phosphate devices have been cleared as substantially equivalent to calcium sulfate devices.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514.

Voluntary standards with which Formagraft Collagen Bone Graft Matrix complies include ASTM F1185 *Standard Specification for Composition of Hydroxylapatite for Surgical Implants*, ASTM F1088, *Standard Specification for Composition of Beta-Tricalcium Phosphate for Surgical Implantation*, ANSI/AAMI/ISO 11137 *Sterilization of Health Care Products - Radiation Sterilization,* and AAMI TIR 27 *Sterilization of health care products—Radiation sterilization—Substantiation of 25 kGy as a sterilization dose—Method* VD_{max}.

A Special Control that applies to Formagraft Collagen Bone Graft Matrix is the FDA CDRH guidance document *Class II Special Controls Guidance: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry & FDA*, June 2, 2003.

INTENDED USE

Formagraft Collagen Bone Graft Matrix is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. The product should be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process. The bone graft can be mixed with autogenous bone marrow prior to use at the physician's discretion. In weight bearing situations, Formagraft is to be used in conjunction with internal or external fixation devices. The fracture defect treated with Formagraft should not exceed 30 mL.

DEVICE DESCRIPTION

Formagraft is a bone graft substitute consisting of resorbable purified fibrillar collagen and partially resorbable hydroxyapatite/tricalcium phosphate (HA / β-TCP) ceramic. The bovine fibrillar collagen component is biocompatible and has low immunogenicity, making it a suitable material for providing a scaffold around which new bone can grow. Both hydroxyapatite (HA) and beta-tricalcium phosphate (β-TCP) ceramic are radiopaque and highly biocompatible. HA is a polycrystalline substance with a stoichiometry similar to bone mineral and is minimally resorbed as bone grows into the scaffold. The porous β-TCP ceramic has a stoichiometry similar to amorphous biologic precursors to bone. In addition, it is biodegradable and its biodegradation products can be reconstituted by the body to form new bone mineral, allowing for bone deposition to occur. The porous HA / β-TCP ceramic has been shown to possess an osteoconductive property for filling bone defects and it can evoke a biologic response similar to that of bone.

EQUIVALENCE TO MARKETED PRODUCT

R and D Medical, LLC submits the following information to demonstrate that, for the purposes of FDA's regulation of medical devices, Formagraft Collagen Bone Graft Matrix is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices.

The intended use, design and functional characteristics of Formagraft Collagen Bone Graft Matrix and the predicate devices are substantially the same. These devices include Orquest, Inc. Healos Bone Graft Material (K012751); NeuColl, Inc. Collagraft Strip Bone Graft Matrix (K000122); Berkeley Advanced Biomaterials Inc. Bi-Ostetic (K023703) and Orthovita Vitoss Scaffold Foam (K032288). These devices all are intended to fill voids or gaps in osseous defects, are not intended to be load-bearing and consist of a variety of calcium compounds and, in three cases, collagen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 7 2005

R and D Medical, LLC
C/o Mr. Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K050789
Trade/Device Name: Formagraft™ Collagen Bone Graft Matrix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: March 25, 2005
Received: March 28, 2005

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050789

Device Name: Formagraft™ Collagen Bone Graft Matrix

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050789